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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/771,845

02/04/2004

Andrew G.C. Frazier

MVMDINC.019A

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03/12/2009

KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

RYCKMAN, MELISSA K

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/771,845	Applicant(s) FRAZIER ET AL.	
	Examiner MELISSA RYCKMAN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-16 and 48-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-16 and 48-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/11/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/11/08 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7,10-13,15,16,48-56 are rejected under 35 U.S.C. 103(a) as obvious over Shaw et al. (U.S. Patent No. 6,080,182) and further in view of Peavey et al. (U.S. Pub. No. 2003/0225421).

Shaw teaches a method of closing a patent foramen ovale having a septum primum and a septum secundum (Figs. 7A,7B), comprising:

- providing a closure device having a proximal end (182), a distal end (183), a proximal segment (182), an intermediate segment (202) and a distal segment (183), the proximal and intermediate segments defining a first clip-shaped portion (112) and the intermediate and distal segments

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defining a second clip-shaped portion (left portion of 201 in Fig. 32A), wherein the closure device is self-expandable to a deployment shape wherein the proximal, intermediate and distal segments are generally parallel to one another (Fig. 32A)

- deploying the closure device within the patent foramen ovale (Fig. 7,32C) such that the second clip-shaped portion is positioned over a tip of the septum primum and the first clip-shaped portion is positioned over a tip of the septum secundum, with the intermediate segment lying in a channel between the septum primum and the septum secundum
- locking the position of the proximal segment, the intermediate segment and the distal segment of the closure device after deployment with a locking element (removal of 152 causes the element to lock, as the element has shape memory and automatically locks onto the tissue after removal of element 152) that is separate from the proximal segment, intermediate segment and the distal segment
- wherein the closure device when deployed exerts a force to draw the septum primum and septum secundum together (Fig. 7,32C)
- the intermediate and distal segments of the closure device when deployed are positioned along surfaces of the septum primum and the proximal and intermediate segments of the closure device when deployed are positioned along surfaces of the septum secundum (Fig. 7,32C)

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- the first clip-shaped portion and second clip-shaped portions are integrally formed (Fig. 32A)
- the first clip-shaped portion and second clip-shaped portions are made of wire (Fig. 32A)
- the first clip-shaped portion and second clip-shaped portions when the device is deployed forms generally an S-shape (Fig. 32A)
- each clip-shaped portion is formed from two adjacent loops connected by a connecting portion (Fig. 32A)
- deploying the closure device comprises releasing the closure device from a detachment element provided on the device (200)
- the closure device is held in its elongate configuration distal to a deployment catheter (210, Fig. 36)
- the closure device is delivered by positioning a catheter between the septum primum and septum secundum (Figs. 7A,32C)
- the closure device includes a plurality of eyelets (183,212,182), and the closure device is releasably attached to the delivery device
- the intermediate segment comprises at least two side-by-side wire portions (201)
- the locking element is provided as part of the closure device (Fig. 32B, 152 is part of the closure device)

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- the locking element connects to the proximal and distal ends of the device, and locking the position of the closure device after deployment comprises longitudinally shortening and radially expanding the device (Fig. 32C)
- the locking element remains within the patent foramen ovale upon deployment (Fig. 32B)
- the locking element comprises a locking string (152 is considered a string, as the applicant does not provide structure for the string, and 152 can be considered a string) connected to eyelets provided on the closure device.

Shaw teaches the claimed invention including using the device with heart defect, but fails to specify the type of heart defect including a patent foramen ovale (PFO), however Peavey teaches using a similar invention with a patent foramen ovale with the septums as described in the claims (Fig. 11). It would have been obvious to one of ordinary skill in the art to use the defect of Peavey with the device of Shaw as it is well known in the art that a PFO is a common defect as described in Peavey.

Claims 1,10,49,52,55, and 56 are rejected under 35 U.S.C. 103(a) as obvious over Shaw et al. (U.S. Patent No. 6,080,182) and further in view of Peavey et al. (U.S. Pub. No. 2003/0225421) and Akerfeldt et al. (U.S. Patent No. 6,508,828 B1).

Shaw teaches a method of closing a patent foramen ovale having a septum primum and a septum secundum (Figs. 7A,7B), comprising:

- providing a closure device having a proximal end (182), a distal end (183), a proximal segment (182), an intermediate segment (202) and a distal

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segment (183), the proximal and intermediate segments defining a first clip-shaped portion (112) and the intermediate and distal segments defining a second clip-shaped portion (left portion of 201 in Fig. 32A), wherein the closure device is self-expandable to a deployment shape wherein the proximal, intermediate and distal segments are generally parallel to one another (Fig. 32A)

- deploying the closure device within the patent foramen ovale (Fig. 7,32C) such that the second clip-shaped portion is positioned over a tip of the septum primum and the first clip-shaped portion is positioned over a tip of the septum secundum, with the intermediate segment lying in a channel between the septum primum and the septum secundum
- wherein the closure device when deployed exerts a force to draw the septum primum and septum secundum together (Fig. 7,32C)

Shaw teaches the claimed invention but does not teach a separate lock that remains in the body after deployment, however Akerfeldt teaches a lock (42, Fig. 16) that is separate from the proximal, distal and intermediate segments, and remains within the body after deployment. It would have been obvious to one of ordinary skill in the art to use the lock of Akerfeldt with the device of Shaw, as the lock aids in keeping the device in the desired location.

Shaw teaches the claimed invention including using the device with heart defect, but fails to specify the type of heart defect including a patent foramen ovale (PFO),

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however Peavey teaches using a similiar invention with a patent foramen ovale with the septums as described in the claims (Fig. 11). It would have been obvious to one of ordinary skill in the art to use the defect of Peavey with the device of Shaw as it is well known in the art that a PFO is a common defect as described in Peavey.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773